K112330

FEB 16 2012

Kowa Kowa Company, Ltd.

ELECTRONICS & OPTICS DIVISION
4-14, NIHONBASHI-HONCHO 3-CHOME,
CHUO-KU, TOKYO 103-8433 JAPAN
TEL: +81-(0)3-3279-7646 FAX: +81-(0)3-3279-7621

510(k) Summary

Submitter information:

Applicant:	Kowa Company, Ltd. 4-14, Nihonbashi-honcho 3-Chome Chuo-ku, Tokyo, 103-8433 Japan Phone: +81-3-3279-7646 Fax: +81-3-3279-7621
Contact:	Hiroyuki Koide
Date summary prepared:	August 10, 2011

Device identification:

Device trade name:	KOWA VX-20
Classification name:	Camera, Ophthalmic, AC-powered System, Image Management, Ophthalmic
Product code:	HKI, NFJ

Identification of predicate devices:

Kowa Company believes that this device is substantially equivalent to:

KOWA VX-10α manufactured by Kowa, 510(k)# K091683,
Canon CX-1 Retinal Camera manufactured by Canon, 510(k)# K092565.

Device description:

The KOWA VX-20 is a retinal image shooting device which can take images with Mydriatic, Non-mydriatic, Fluorescein Angiography (FA), Red Free (RF), and Fundus AutoFluorescence angiography (FAF).

The KOWA VX-20 is equipped with the filing function of captured images and the stored retinal images can display in the LCD monitor.

The KOWA VX-20 is equipped with USB ports and an Ethernet port to be able to transfer images to the external device.

Intended use:

The KOWA VX-20 is intended for taking pictures of retinal images with mydriatic or without mydriatic.

Technical characteristics:

Performance

The KOWA VX-20 is tested in accordance with ISO10940. The KOWA VX-20 met all requirements of the standard.

Electrical safety
To guarantee Electrical safety, IEC60601-1 test was performed. The KOWA VX-20 met all requirements of the standard.

Electromagnetic compatibility
To guarantee Electromagnetic compatibility, IEC60601-1-2 test was performed. The KOWA VX-20 met all requirements of the standard.

Optical safety
To guarantee Optical safety, ISO15004-2 evaluation was performed. The KOWA VX-20 met all requirements of Group 2 instrument in the standard.

Software evaluation
To make sure Software validity of the KOWA VX-20 embedded softwares, evaluation based on FDA guidance, "Guidance for the content of premarket submissions for software contained in medical devices, 2005", was performed.
The levels of concern of these software items are moderate.
The validation of these software items is performed as a part of system function test. All functions are tested and confirmed good working to required items.

Biocompatibility
To guarantee biocompatibility, biocompatibility assessment was performed. The materials were used the same of the other legally marked devices in US or were evaluated under the Material Safety Data Sheet (MSDS).

Risk Management
The KOWA VX-20 was evaluated in accordance with ISO14971: 2007. The risk management of the device was deemed satisfactory. Remaining risks will be noted in the user manual, so users will be able to avoid them.

Conclusion
KOWA VX-20 is equipped with the fundamental technology to the predicate devices for retinal image capturing and also delivers the equivalent level of safety. Therefore, it is concluded that there is no difference in the basic functions and safety between KOWA VX-20 and the predicate devices.

Table A: Predicate Device Comparison			
Device Name	**KOWA VX-20**	**KOWA VX-10α**	**Canon CX-1 Retinal Cameras**
510(k) number	-	K091683	K092565
Indications for use	Same as KOWA VX-10α	The device is intended for taking pictures of fundus images with mydriatic or without mydriatic.	The device is intended to be used for taking digital images of retinal of human eye with non-mydriatic and mydriatic.
Photography mode	Non-mydriatic, Mydriatic color, FA, Red free, FAF (optional)	Non-mydriatic Mydriatic color FA	COLOR FLUO (FA) RED FREE COBALT FAF

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Kowa Company, Ltd.
c/o Mr. Hiroyuki Koide
Section Manager, Regulatory Affairs Section
4-14 , Ninonbashihonco 3-Chrome
Chuo-ku, Tokyo 103-8433
Japan

FEB 16 2012

Re: K112330
Trade/Device Name: KOWA VX-20
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI, NFJ
Dated: January 19, 2012
Received: January 20, 2012

Dear Mr. Koide:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.0 Indications for Use

510(k) Number (if know): K112330

Device Name: KOWA VX-20

Indications for Use:

The KOWA VX-20 is intended for taking pictures of retinal images with mydriatic or without mydriatic.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device

Marsha L. Burke Nicholas

...Neurological and Ear,

...Devices

...mber K112330